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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,367	09/24/2003	Mark W. Kroll	A03P1066	1862

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PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER
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SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/671,367	Applicant(s) KROLL ET AL.	
	Examiner Kennedy Schaetzle	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/24/03, 1/13/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12, drawn to an implantable lead, classified in class 600, subclass 377.
  - II. Claims 13-18, drawn to an apparatus and method for rejecting far-field signals, classified in class 600, subclass 509.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the distal and proximal electrodes to be connected together and electrically connected to a first terminal, with the intermediate electrode connected to a second terminal. The subcombination has separate utility such as for use in applying stimulation energy to the heart.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mr. Derrick Reed on April 19, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 3766

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Objections***

5. Claim 7 is objected to because of the following informalities: a typographical error appears on the last line. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

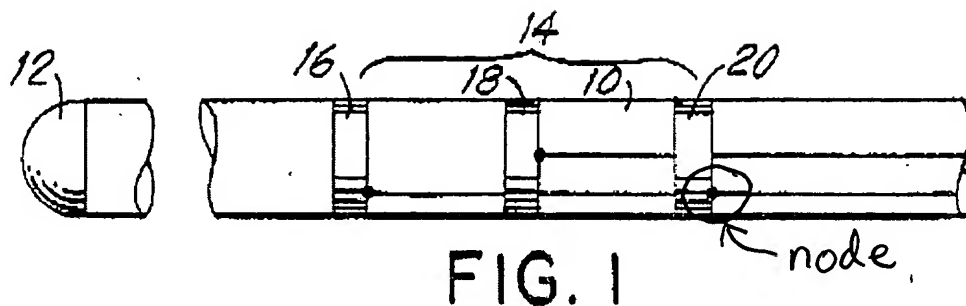
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Astrinsky (Pat. No. 4,892,102).

Regarding claim 1, Astrinsky shows a lead body 10 having a proximal and a distal end, carrying a plurality of electrodes in spaced-apart relationship along the distal end of the lead body, said plurality of electrodes comprising a distal electrode 16, a proximal electrode 20 and an intermediate electrode 18 positioned between the distal and proximal electrodes, the distal and proximal electrodes being connected together and electrically connected to a first terminal contact and the intermediate electrode being electrically connected to the second terminal contact (see col. 2, lines 52-58). While Astrinsky is not concerned with the proximal end of the lead and thus does not bother with showing a connector assembly, such a feature is inherently necessary if the device is to mechanically and electrically connect to a pacer or measuring/sensing device such as discussed in col. 2, lines 56-58. A similar comment applies to claim 7.

The limitations of claims 2-5, 8, 10 and 11 are clearly shown.

Regarding claim 9, the examiner considers the point circled below to be a node point.



***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Astrinsky in view of Kroll et al. (Pat. No. 5,265,623).

Astrinsky does not discuss the use of a cardioverting-defibrillating electrode carried along the distal end of the lead body and concomitantly does not discuss the use of a third lead conductor within the lead body for coupling the electrode to a third terminal on a connector assembly. The decision as to which types of electrodes are required on a cardiac lead would clearly have been seen as a matter of obvious design dependent upon the condition of the patient in which the lead is implanted. A patient prone to fibrillation, for example, would obviously benefit from a lead design incorporating cardioverting-defibrillating electrodes in order to allow for more comprehensive and flexible treatment options. The use of leads with pacing, sensing and defibrillating electrodes is old and well known in the cardiac electrical treatment arts—especially given the fact that such leads simplify the implant process by enabling a multitude of different electrodes to be placed with the insertion of a single lead. Kroll et al., for example, discloses a lead with both pace/sense ring electrodes and high-energy defibrillation/cardioversion electrodes. Kroll et al. further teach in the text adjoining cols.

3 and 4 that the lead may be configured to suit the particular application at hand. Given that such lead systems are known in the prior art as shown by Kroll et al., and given that such leads are advantageous in situations where the patient requires a variety of different treatment regimens due to differing conditions, artisans of ordinary skill would have seen the provision of a cardioverting-defibrillating electrode and its associated conductor on the lead of Astrinsky to be blatantly obvious.

### ***Conclusion***


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
April 19, 2006

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER